DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

August 22, 2002

VIA FEDERAL EXPRESS—NEXT DAY

Vickie S. Kelley and Michael C. Kelley, Co-Owners
Kelley's Katch Caviar
140 Jaggers Lane
Savannah, TN 38372

Warning Letter No. 02-NSV-37

Mrs. and Mr. Kelley:

We inspected your firm located at 140 Jaggers Lane, Savannah, TN, on March 5 & 6, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123) and the Food Labeling regulations (21 CFR Part 101). These deviations, most of which were previously brought to your attention in our letters dated February 5, 2001 and July 17, 2001, cause your paddlefish roe to be in violation of sections 402(a)(4) and 403 of the Federal Food, Drug, and Cosmetic Act (the Act). Seafood HACCP and food labeling information is also available through links in FDA's home page at www.fda.gov.

The Seafood HACCP deviations were as follows:

- You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points for each of the identified food safety hazards, to comply with 21 CFR 123.6(a) and 123.6(c)(2). However, your firm's HACCP plan for paddlefish caviar does not list the critical control points of "receiving in-coming paddlefish caviar (salt-cured paddlefish roe) from other processor" for controlling the food safety hazard of pathogen growth/toxin formation (i.e., *C. botulinum/S. aureus*.)

- You must have a HACCP plan that, at a minimum, lists the critical control points for each of the identified food safety hazards to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for paddlefish caviar does not list the critical control point of product storage for controlling the food safety hazard of *Clostridium botulinum*.

- You must retain records at the processing facility for at least 1 year after the date they were prepared in the case of refrigerated products, to comply with 21 CFR 123.9(b)(1). However, your firm's temperature chart records for paddlefish caviar were only retained for two or three months.

- Failure to prepare sanitation monitoring records, as required by **21 CFR 123.11(c)**.

- Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for paddlefish caviar at the "Receiving Screened Roe and roe is Weighed & Then Salted" critical control points to control pathogen growth and toxin formation (e.g., *Clostridium botulinum*) is not appropriate. You did not list how the cause of the deviation would be corrected. In addition, you did not list how you would ensure that the product would not enter commerce before the deviation is corrected.

In addition, your paddlefish roe labels are in violation of Section 403 of the Act and in violation of FDA's Food Labeling regulations, 21 CFR Part 101, as follows:

- Your retail paddlefish roe is misbranded within the meaning of Section 403(a)(1) in that the statement of identity **"caviar"** is misleading. The name **"caviar"** unqualified may only be applied to sturgeon roe. Caviar prepared from the roe of other fish must be labeled to show the name of the fish from which it is prepared. For example, an article prepared by this special method from roe of other fish may be labeled "_____" caviar, the blank to be filled in with the common or usual name of the fish from which the roe was taken. All words in the name should be in type of substantially the same size and prominence.

- Your ½ gallon plastic bucket of finished bulk paddlefish caviar is misbranded within the meaning of section 403(i)(2) of the Act in that it is fabricated from two or more ingredients, but the label fails to bear the common or usual name of each ingredient in the product (21 CFR 101.4(a)(1).

We also noted that your bulk paddlefish roe label does not have a refrigeration statement. As explained in FDA's Guidance on Labeling of Foods That Need Refrigeration by Consumers, FDA recommends that roe with less than 20% water phase salt, packaged in reduced oxygen packaging be labeled with a statement such as "IMPORTANT Must Be Kept Refrigerated To Maintain Safety." You may find this guidance document at: http: //www.cfsan.fda.gov/~lrd/fr970224.html.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

Please respond in writing within fifteen (15) working days from the receipt of this letter. Your response should outline the specific steps you have taken to correct the above deficiencies in your HACCP plan and product labeling. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure and/or injunction, without further notice.

Your reply should be addressed to the attention of Karen Gale Sego, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Carl E. Draper
Director, New Orleans District

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Enclosure:
Guidance on Labeling of Foods That Need Refrigeration by Consumers